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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/071,620

02/08/2002

Gholam-Reza Zadno-Azizi

38349-0102C

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06/29/2004

FISH & RICHARDSON, PC  
12390 EL CAMINO REAL  
SAN DIEGO, CA 92130-2081

EXAMINER

CHATTOPADHYAY, URMI

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/071,620	ZADNO-AZIZI ET AL.	
	Examiner	Art Unit	
	Urmi Chattopadhyay	3738	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 16-53 is/are pending in the application.
- 4a) Of the above claim(s) 16-24, 28-30 and 34-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-27, 31-33, 52 and 53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 February 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/14/04</u>   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Request for Continued Examination***

1. The request filed on 1/14/04 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on Application No. 10/071,620 is acceptable and a RCE has been established. An action on the RCE follows.

### ***Response to Amendment***

2. The amendment filed 3/24/04 has been entered. Claim 53 has been added and the changes to claims 25 and 52 have been approved by the examiner. Claims 16-53 are pending, of which claims 16-24, 28-30 and 34-51 remain withdrawn from consideration. The claims being considered for further examination on the merits are 25-27, 31-33, 52 and 53.

### ***Information Disclosure Statement***

3. The information disclosure statement (IDS) submitted on 1/14/04 has been considered by the examiner. A number was missing from the one patent application publication cited in the IDS; the examiner corrected the citation and considered the reference.

### ***Drawings***

4. The drawings are objected to because in Figure 5, there are two "34". It appears that the top occurrence should be changed to --30--. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

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5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "58" (page 8, line 19) and "64" (page 8, line 21) have both been used to designate the "passage" in Figure 9. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. Any correction to the drawing must also be reflected in the written specification.

### *Claim Objections*

6. Claim 26 is objected to because it repeats limitations already claimed in claim 25, on which it depends. Claim 26 requires the device to "further comprises a frame" when claim 25 already claims a frame, and there is no support in the specification for two frames. The examiner will interpret the frame of claim 26 to be the same as the frame of claim 25 for examination purposes. Also, the claim 26 limitation of "the frame is expanded within a pulmonic passageway to an expanded state" does not further limit the claim 25 limitation of "permitting the frame to self-expand within the pulmonic passageway". Claim 26 should be rewritten only to include new limitations.

7. Claim 31 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 25, on which claim 31 depends, already requires the flow control device to be anchored to a pulmonic passageway after pulmonic placement by requiring the step of "permitting the frame to self-expand within the pulmonic passageway sufficiently to

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anchor the flow control device within the pulmonic passageway” after placing the device within the pulmonic passageway.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 33 is indefinite because it is unclear how the resilient seal seals against a pulmonic passageway *during* pulmonic placement when it appears that the resilient seal is required by claim 25 to seal with the wall of the pulmonic passageway *after* device placement. Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 25-27, 31-33, 52 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leonhardt et al. (USPN 5,957,949 as cited in applicant's IDS) in view of

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Andersen et al. (USPN 5,411,552 as cited in previous office action) and Lentz (USPN 5,522,881).

Leonhardt et al. discloses a method of treating a patient using a flow control valve prosthesis with all the elements of claim 25, but is silent to placing the flow control device specifically in a pulmonic passageway of the patient and to the self-expansion of the frame within the passageway being sufficient to anchor the device therein. See column 1, lines 11-20 for placing in any passageway that flow control is desired a flow control device (20). See Figure 4 for the flow control device having a resilient seal (24), a frame (26), and a valve body (22). See Figures 9A-9B, column 10, lines 53-58 and column 11, lines 13-15 for permitting the frame (26) to self-expand within a passageway and column 5, lines 45-49 for the resilient seal (24) sealing with a wall of the passageway so as to prevent fluid flow between the resilient seal and the wall of the passageway. Andersen et al. teaches that it is old and well known for a flow control valve prosthesis to be used in several different passageways, including the aorta and the pulmonary artery. See column 3, lines 43-52. It would have been obvious, therefore, to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Andersen et al. to use the flow control device of Leonhardt et al., which is disclosed as being used in the aorta or any other passageway requiring flow control, in the alternative passageway of the pulmonary artery (pulmonic passageway). Lentz teaches a stent-graft (10) wherein the stent (28) is designed to radially self-expand with a force sufficient to anchor the stent-graft (10) within a lumen (32) of a vessel (34) to form a liquid seal therein without placing disruptive force or undue pressure on the intraluminal walls. See Figure 7 and column 5, lines 8-9 and 17-21. Because the super elasticity of the self-expanding frame (26) of Leonhardt allows it to "conform to and seal

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against the dramatically different structures occurring within vessel walls and valve locations” (column 4, lines 60-65), it would have been obvious to one of ordinary skill in the art that the self-expansion force of the frame (26) that is forming a seal with the vessel is sufficient to anchor the device within the vessel. The expansion balloon (154) will then be used to simply maintain the anchored position of the device during the remainder of the deployment procedure when displacement forces acting on the device will be greater than the forces acting on the device during use.

Claim 26, see Figure 4 for a frame (26) secured to (column 5, lines 61-62) the flow control device (20). See Figures 9A-9D for the flow control device being placed with the frame in an insertion state and the frame being expanded within the passageway to an expanded state.

Claim 27, see column 4, lines 26-28 for the frame (26) being comprised of a material having spring resilience. See Figures 9A-9D and columns 10-11, lines 53-21 for releasing the preconstraint (106) to allow the frame (26) to expand to an expanded state so as to engage the passageway.

Claim 31, see column 11, lines 3-9 and 20-22 for anchoring flow control device (20).

Claim 32, see column 11, lines 3-22 for resilient seal sealing against passageway during placement.

Claim 33, see column 1, lines 11-13 for one-way valve providing one direction fluid flow.

Claim 52, see column 6, lines 25-26 for a frame (26) coupled to the valve body (22).

With respect to claim 53, see Figures 9A-9D. The definition of “distort”, according to [www.webster.com](http://www.webster.com) is “to twist out of a natural, normal, or original shape or condition”. The

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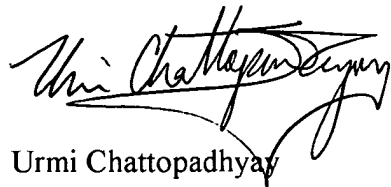
definition of “distort” according to Webster’s II New Riverside University Dictionary is “to twist out of proper shape or relation”. The term “distort” is given its plain meaning (dictionary definitions) because the specification does not clearly set forth a definition explicitly and with reasonable clarity, deliberateness and precision of the term. Because the valve body is reverting back to its natural and normal shape to provide as a patent one-way valve when the frame expands, the valve body does not “distort” (as defined) when the frame expands.

***Response to Arguments***


12. Applicant's arguments with respect to claims 25-27, 31-33, 52 and 53 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner’s supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 872-9306. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay  
Art Unit 3738



David J. Isabella  
Primary Examiner